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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,872	03/16/2001	Peter Zhu	JOHNA.058A	7471

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EXAMINER

CROSS, LATOYA I

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 08/26/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/810,872

Applicant(s)

ZHU ET AL

Examiner

LaToya I. Cross

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 10-23 and 25-33 is/are pending in the application.
- 4a) Of the above claim(s) 15-23, 25-29 and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 10-23 and 25-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to Applicant's amendment filed on June 10, 2003 and entered as Paper No. 7. Claims 1-7, 10-23 and 25-33 are pending. Claims 15-23, 25-29 and 31 are withdrawn from consideration as being directed to non-elected subject matter.

Election/Restrictions

1. Applicant's election without traverse of group I, claims 1-7, 10-14, 30 and 32 in Paper No. 7 is acknowledged.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-7, 11, 12, 14, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 4,471,055 to Opp.

Opp teaches a process for determining whether the concentration of aldehyde in a sample is in excess of a predetermined concentration. The predetermined concentration of aldehyde is the point of interest of aldehyde. The method for determining whether aldehyde is present in a predetermined concentration taught by Opp comprises mixing the test sample with a first reaction system which reacts with carbonyl group in aldehydes, followed by reaction of the resultant product with a second reaction system, which reacts with any unreacted aldehyde, and detecting any visual formation of a second reaction product, as recited in claim 1 (col. 14, lines 7-41). The aldehydes to be tested are those used in disinfecting systems (in germicidal

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capacities) having at least one -CHO moiety, which includes glutaraldehyde, phthaldehyde, and formaldehyde, as recited in claims 6 and 7. The first reaction system includes reactants which form a colorless derivative of aldehyde, such as hydroxylamine or hydrazine, as recited in claim 5 (col. 4, lines 15-30). The second reaction system includes reactants that form aldehyde derivatives which are visually distinguishable from the first reaction products, such as amino acids, including glycine and lysine, as recited in claims 2-4 (col. 4, lines 38-55). Opp teaches that the first reaction products are colorless, as recited in claim 10 (col. 4, lines 15-17, col. 14, lines 42-43). With respect to claim 11, Opp teaches that the amount of first reaction system completely transform the amount of aldehyde equal to the predetermined amount, while the second reaction system provides a visual color where the amount of aldehyde exceeds the predetermined amount. Where the amount of aldehyde is less than the predetermined amount (1% for disinfecting processes), it would be inherent that no color would form since there would not be an excess amount of aldehyde to react in the second reaction system. With respect to claim 12, each of examples I-IX of Opp teaches providing a fixed volume of sample (0.1-1 milliliter) to which the reactants are added. Further, with respect to claim 14, Opp teaches that the fixed volume of test sample is added to a 7 cc reaction container (measuring device), where the reaction container the first reaction system reagents (hydroxylamine or hydrazine).

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be anticipated, within the meaning of 35 USC 102(b) in view of the teachings of Opp '055.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459

(1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Opp in view of US Patent 4,703,763 to McAlister et al.

The disclosure of Opp is described above. Opp fails to teach loading a fixed volume of test sample into a measuring device having a liquid impermeable membrane.

McAlister et al teach a device for sample a pre-set volume of test sample. The device is a syringe-type measuring device having a plug element (filter) arranged to be air-permeable, but liquid impermeable. This allows enough fluid sample to be up taken into the syringe and then allow the fluid flow to stop when the predetermined amount is taken in. See col. 1, lines 41-59. It would have been obvious to one of ordinary skill in the art to use the device of McAlister et al to measuring an exact amount of test sample in carrying out the method of Opp. Such will prevent using excess sample. Since it is important that the amount of reagents in the method of Opp be exact for the amount of sample, using the device of McAlister et al will alleviate false positives due to incorrect reagent to sample ratios.

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Therefore, for the reason set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 USC 103, in view of the teachings of Opp and McAlister et al.

7. Claims 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 4,521,376 to Witonsky et al in view of US Patent 6,436,716 to Wu.

Witonsky et al teach a method for determining whether the concentration of disinfectant/sterilant exceeds a predetermined value. The method tests for sufficient glutaraldehyde amounts in a disinfecting solution. The method involves contacting a test sample with a test strip impregnated with a sulfite compound and an amino acid compound. The sulfite compound is sodium sulfite (col. 2, line 24). The amino acid is glycine (col. 2, line 27). The method by which excess glutaraldehyde is to be determined is explained in Wu. Glutaraldehyde reacts with sulfite to form a sulfite addition product, which reacts with glycine to form sodium glycinate. Excess glutaraldehyde reacts with sodium glycinate to form a colored product. Thus, the sulfite serves as a first reactant to react with the carbonyl group in the aldehyde and glycine serves as the second reactant to react with remaining aldehyde in the sample that is unreacted. See col. 2, lines 39-52.

Witonsky et al teaches using sodium sulfite, but fail to teach using sodium bisulfite. Wu teaches that both sodium sulfite and sodium bisulfite are effective in processes for determining the presence of aldehydes (col. 1, line 65 – col. 2, line 12). It would have been obvious to one of ordinary skill in the art to substitute sodium sulfite in Witonsky et al for sodium bisulfite, since both are known in the art to be suitable in determining the presence of aldehydes. See MPEP 2144.06.

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With respect to claim 33, where Applicants recite that the first reaction step is kinetically and thermodynamically favored over the first second reaction step, such would have been obvious to the ordinarily-skilled artisan because Wu teaches that aldehyde in the sample reacts with the sulfite first prior to reacting with glycine. Thus, the first reaction step would obviously have to be favored over the second reaction step.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 USC 103, in view of the teachings of Witonsky et al and Wu.

Response to Arguments

8. Applicant's arguments filed June 10, 2003 have been fully considered but they are not persuasive. With respect to the rejection over Opp, Applicants argue that Opp fails to teach that the amino containing compound and the compound that reacts with a carbonyl group are contacted with the test sample at the same time. The Examiner disagrees because the method of Opp, as defined by the claims at col. 14, lines 7-40, states that the sample, first reaction system (hydroxylamine or hydrazine) and the second reaction system (amino containing compound) are combined as a mixture. Therefore, both of the reaction systems are together in the method for determining excess aldehyde. It appears that Applicants' concern lies in the fact that the reaction systems are not simultaneously incorporated into the container having the sample. The claims, however, are not limited to simultaneous incorporation. Applicants' use of the phrase "are contacted with the sample in a container at the same time", in its broadest interpretation means merely that the amino containing compound and the compound to react with a carbonyl group both contact the sample at the same time. Such is taught by Opp because all the components are mixed together. Further, even if the claims were amended to

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recite simultaneous incorporation of the components into a container with the sample, such would not be patentably distinct from Opp, without a showing that simultaneous incorporation would have an unexpected result on the method that Opp fails to teach. Applicants state that it is unexpected that different colors will be observed when both reactants are present at the same time. In response, Opp teaches that both reactants are present at the same time. Also, Opp teaches that a first reaction product (a colorless product) is formed when the first reaction system contacts a predetermined minimum concentration of aldehyde and a second reaction product (a colored product) is formed when the second reaction system contacts an excess of aldehyde. Thus, Opp teaches that when both reactants are present at the same time, two different reaction products are formed. Therefore, Applicants' observance is not unexpected.

With respect to the rejection over Opp in view of McAlister, Applicants argue that McAlister fails to teach that both the first and second reactions system are present in the measuring device. The Examiner would like to point out that McAlister is used only for its teaching that the measuring device may have a liquid permeable membrane. Opp teaches using a measuring device (pipette) containing both the first and second reaction systems (col. 8, lines 3-26), where the sample is taken up into the measuring device to contact the first and second reaction systems. McAlister merely provides motivation for using a measuring device having a liquid permeable membrane.

With respect to Applicants' argument regarding claim 30 and Witonsky et al, the arguments are moot in view of the above rejections. Claim 30 is now rejected over Opp. Claim 32 is now rejected over Witonsky et al. Applicants' concern regarding Witonsky's teaching of test strips rather than solutions is addressed because Opp teaches using solutions.

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9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

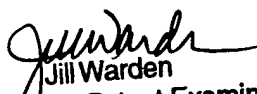
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 703-305-7360. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

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August 22, 2003


Jill Warden
Supervisory Patent Examiner
Technology Center 1700